BIA submission:
Invest 2035: The UK's Modern Industrial Strategy

BIA response to the industrial strategy green paper

About the BIA

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world changing innovation. Our members include start-ups, biotechnology and innovative life science companies, large pharmaceutical companies, universities, research centres, tech transfer offices, incubators and accelerators, and a wide range of life science service providers: investors, lawyers, IP consultants, and IR agencies. We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

Overall comments

The industrial strategy green paper rightly identifies life sciences as a strategic area of UK strength that is primed for growth. To capture a greater share of internationally mobile investment in life science and spur domestic businesses to boost their investment and scale up their growth, the strategy should:

1. **Boost existing partnership working structures and policy**

The UK life science sector has established and successful working partnerships with the UK government through the Life Science Council and the Office for Life Sciences. These should be strengthened as part of the Industrial Strategy.

BIA worked with the now-Chancellor and Science and Health Secretaries ahead of the general election to produce detailed policy documents like A Prescription for Growth1, which set clear priorities, and are deeply engaged on the pensions reform and Mansion House agenda with HM Treasury and the Department for Work and Pensions. The strategy should focus on what is working, and there is no need to reinvent the wheel.

[1] The Labour Party: A prescription for growth (2024).

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2. **Ensure focus is maintained on the key sub sectors and technologies in life science:**
    - Engineering biology[2]
    - Cell and gene[3]
    - Techbio – the intersection of AI and data with life sciences[4]
    - Genomics (extending to multiomics)[5]
    - mRNA[6]
    - Additionally, the UK strength in life sciences and engineering biology is enabling innovative start-ups and scale-ups to develop biosolutions to many of humankind's greatest challenges beyond health, such as climate change and world hunger. BIA has coined this Deep Biotech to highlight its growth potential, which is also deserving of support within the industrial strategy[7]

3. **Address the key barriers to growth, which are:**
    - Access to finance for scale-up
    - Training and up-skilling the next generation of workers and entrepreneurs
    - Regulation (inc. health data, duplication with the EU)
    - Global trade disruption/Brexit/ threat of tariffs

4. **Create the right conditions for increased investment via:**
    - Competitive tax and business environment
    - Smart procurement - Buying from UK scalers
    - Getting UK health data right
    - Maintenance and advocacy for Intellectual Property Rights globally

We would be happy to engage on any of these policy details with officials and ministers either in writing or in person – we understand you are likely to be inundated with responses, but please do get in touch if there's anything additional you would find of use, and we will provide the expertise and data.

[2] BIA, DBT: Power of biology: The UK is engineering biology for global good. (2022).
[3] BIA: UK cell and gene therapy: Leading the path to transformative medicine. (2024).
[4] BIA: Tech Bio: UK leads innovation further. (2024).
[5] BIA: Genomics nation 2023: A genomics-powered UK life science ecosystem (2023).
[6] BIA: mRNA revolution: A new generation of medicine. (2024).
[7] BIA: Deep Biotech. (2024).

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Responses to the consultation questions

Sector Methodology

1. **How should the UK government identify the most important subsectors for delivering our objectives?**
2. **How should the UK government account for emerging sectors and technologies for which conventional data sources are less appropriate?**
3. **How should the UK government incorporate foundational sectors and value chains into this analysis?**

Key points:

- Company creation, equity investment, R&D expenditure (in-house and outsourced), patenting and scientific publishing, and job creation are all valuable metrics and signs of high-growth businesses/subsectors at the cutting edge of their sector and should be used to identify subsectors and places to support through the Industrial Strategy
- Do not over-rely on the SIC system, which is not compatible with innovative life sciences, especially for economic analyses
- Industry engagement, primarily through trade associations, should be done early and fully to identify subsectors and technologies that might help deliver the government's objectives
- Emerging, cutting-edge technology where the UK has a competitive advantage could be considered as subsectors or foundational technologies that will contribute most to growth if given targeted support
- Start-ups and scale-ups are the primary source of innovation and growth in life sciences and should be prioritised in the Industrial Strategy

The government is right to focus on growth-driving sectors. The UK cannot be a world-leader in everything, and our future economic growth will inevitably come from areas of strength and competitive advantage. The Industrial Strategy must therefore be targeted, and we welcome the selection of life sciences as one of the eight prioritised sectors.

It is unclear from the green paper what level of granularity is being sought on subsector identification. The paper refers to the SIC system and the BIA identifies biotechnology within the wider life sciences sector (which is not a SIC sector in itself) as the primary SIC subsector driving innovation and growth in the industry. Biotechnology is the manipulation of biological systems to generate new medicines (antibodies, cell and gene therapies etc.) but also new diagnostics, research tools and many other biology-based products. It can be considered analogous to engineering biology, which is generally considered a technology rather than a subsector. Biotech

and engineering biology have been transforming healthcare since the 1980s but are now seen to have the potential to radically reshape production methods in many other sectors.

The SIC system is problematic for value chain analysis as it is outdated and unsophisticated. This is exacerbated because R&D plays such an outsized role in life sciences and biotech, and because R&D and manufacturing are highly fragmented in life sciences. Research, development and manufacture of most life science products involves many specialist companies and supply chains can be hard to decipher from data alone.

For example, the innovative companies that BIA represents generally fall into SIC 72110 (R&D in biotechnology); however, established companies still highly active in R&D but also undertaking manufacturing can use SIC 21100 (Manufacture of basic pharmaceutical products and preparations). Those established companies may acquire the R&D (72110) companies and/or their products, meaning the latter could be considered supplying the former. However, there are also small pharmaceutical manufacturing service companies classed under 21100, which produce medicines for companies classed under 72110; in this case, the manufacturing company is the supplier. We therefore caution reliance on the SIC system, especially when conducting economic analysis to inform the Industrial Strategy.

Economic analyses can also be problematic because they tend to measure traditional metrics, such as production of goods or services for sale (productivity). Whilst this is important in all sectors, it can hide the true economic impact of a sector that has long R&D timelines, such as life sciences (medicines typically take 10-15 years to develop). Measurement of outputs should carefully consider R&D-intensive but non-revenue generating companies when seeking to identify subsectors and places to support through the Industrial Strategy. Company creation, equity investment, R&D expenditure (in-house and outsourced), patenting and scientific publishing, and job creation are all valuable metrics and signs of high-growth businesses/subsectors at the cutting edge of their sector[8].

Industry engagement is a sensible and proven way to understand subsectors beyond the limitations of SIC-based statistics when considering polices for an Industrial Strategy. Trade Associations such as BIA should be engaged early and fully to identify subsectors that might help deliver the government's objectives.

Subsectors in life sciences are often defined by either the technology (e.g. cell therapies, mRNA, AI-driven drug discovery), or application (e.g. cancer, respiratory, neurological). The breadth, depth and strength of UK life sciences means we have opportunities across many, if not all, of these subsectors and/or technologies, however they are defined. However, some are more nascent than others, and it is at this cutting edge that the UK can take advantage of lower levels of international competition to capture significant market share in future growth subsectors/technologies, if the

[8] BIA, London Economics: The effectiveness of R&D tax relief in the life sciences sector. (2024).

Industrial Strategy is correctly targeted. We outline some of these emerging subsectors/technologies where we have competitive advantage in this submission.

Although not technically a subsector, it is critically important to think of start-ups and scale-ups in the Industrial Strategy. They are often the innovators in any sector, but this is particularly true in life sciences. In many cases, multinational companies play the crucial but often supporting role in the later stages of the drug development process, although an increasing number of smaller companies are succeeding in independently taking a medicine all the way from discovery to market, such as Oxford-based Immunocore and Stevenage-based Autolus.[9,10] As a result, emerging life science and biotech companies represented 65% of the global drug development pipeline in 2021, with an additional 7% being developed by them in partnership with larger firms.[11] Despite this outsized contribution, start-ups and scale-ups face the greatest barriers to growth, including access to capital and skills and navigating complex regulatory pathways. Their impact is also not easily measured by traditional econometric methods. They therefore need special consideration and targeted support through any Industrial Strategy.

Sectors

4. What are the most important subsectors and technologies that the UK government should focus on and why?

Key points:

- The most important technologies that the government should focus on are engineering biology, cell and gene therapies, precision medicine, Artificial Intelligence (AI) and 'techbio', functional genomics, and mRNA.
- The most important subsector that the government should focus on is deep biotech, that is, non-health engineering biology companies and their applications across multiple sectors beyond health.

Technologies

Engineering biology. The UK is a world-leader in engineering biology, with a strong academic and R&D base. UK engineering biology companies are at the forefront of innovations such as new therapeutics based on living bacteria to treat a broad range of diseases, or genetically edited mosquitoes that are less able to spread disease.[12] Advances like these make the life sciences one

[9] Immunocore: The UK Medicines and Healthcare products Regulatory Agency (MHRA), Australian Therapeutic Goods Administration (TGA) and Health Canada approve KIMMTRAK® (tebentafusp) for the treatment of unresectable or metastatic uveal melanoma. (2022).
[10] Autolus: Autolus Therapeutics Announces FDA Approval of AUCATZYL® (obecabtagene autoleucel – obe-cel) for adults with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL). (2024).
[11] IQVIA: Emerging biopharma's contribution to innovation. (2024).
[12] BIA: Power of Biology: The UK is engineering biology for global good. (2022).

of the UK's most successful sectors, worth over £94 billion to the UK economy[13] and consistently raising more venture capital than its European counterparts.[14]

It is not just in healthcare where engineering biology is benefitting humankind. The engineering of biology allows us to create bio-based processes and products that can replace traditional and less environmentally sustainable ones, leading us towards a greener, healthier planet and people. In the non-health biotech space, innovative companies have been using fungi to produce proteins as a sustainable alternative to meat, transform whisky production residues into sustainable biofuels,[15] and create insulation materials from mushrooms with a carbon-negative production footprint.[16]

The rise of modern industrial biotechnologies[17], like CRISPR[18] gene editing, is enabling us to engineer biology in groundbreaking ways. This, combined with advancements in big data, AI, genomics, and DNA sequencing, is paving the way for truly disruptive biological innovations. These innovations have the potential to mitigate and counteract any of the UK's and the world's health and sustainability challenges, and need to be deployed at scale to deliver for the UK's growth and net zero mission.

Cell and gene therapies (also known as advanced therapies) The UK has long been a leader in cell and gene therapies, and this has been enabled through targeted Government investment in this area, including through the Cell and Gene Therapy Catapult. UK-based cell and gene therapy companies are at the forefront of scientific developments and are attracting significant investment. The UK also continues to be the leading destination in Europe for clinical trials in cell and gene therapy.[19] Stakeholders across the sector – including industry, academia, government, NHS and patient groups – have already demonstrated an impressive ability to work collaboratively to address challenges and ensure the continued growth of the technology, including through initiatives such as the Advanced Therapy Treatment Centres and the Advanced Therapies Manufacturing Taskforce. It is important that this momentum is maintained in order to unlock the full potential of the UK life sciences sector[20].

Artificial intelligence (AI), machine learning (ML) and technology in life sciences (techbio) are key tools that have the potential to revolutionize the way we understand biology, discover and develop medicines and treat disease. These technologies can be used to improve efficiency in lab

[13] HMT, DSIT, DHSC, OLS: Chancellor reveals life sciences growth package to fire up economy. (2023).
[14] BIA: UK biotech financing 2023. (2023).
[15] Celtic Renewables. (2024).
[16] Biohm. (2024).
[17] University of Cambridge: Life sciences beyond human health: modern industrial biotechnology in the UK. (2023).
[18] Your Genome: What is CRISPR-Cas9? (2023).
[19] BIA: UK cell and gene therapy: Leading the path to transformative medicine. (2024).
[20] BIA: UK cell and gene therapy: Leading the path to transformative medicine. (2024).

experiments, improve the detection and diagnosis of disease, speed up the discovery of new drugs and support clinical trial design. They can greatly improve our health, while vastly improving efficiency and growth in the key areas of health and life sciences.

The intersection of two key growth-driving sectors has significant opportunity in the UK, which is seen as a leader in both AI and life sciences. As an example, Alphabet has chosen to set up their AI and drug discovery company – Isomorphic Labs – not in Silicon Valley, but in London.
Functional genomics technologies enable us to go beyond sequencing genomes and take the next step pivotal step of understanding how these genetic changes result in a disease. Drug targets supported by genetic evidence have been shown to double the probability of reaching market approval[21], demonstrating the strong value of these technologies in drug discovery. Functional genomics technologies are a vital tool in the future of preventative and precision medicine. However, dissecting complex pathways is a huge project, akin to the 100,000 genomics project. Government support is therefore needed to leverage the UK's unique advantage in this area.

Precision and preventative medicine is a key technology of the future, both in life sciences and for the NHS. The term encompasses a variety of tools and techniques which seek to predict, diagnose and treat disease in a far more sophisticated manner than in the past. If the NHS is to succeed in shifting to prevention and to better using technology in healthcare, the government needs to work in partnership with companies in this field. Precision medicine tools can play a key role in identifying patients most at-risk of developing specific complications, providing them with actionable information about their risks, and helping target interventions to them before they experience the most serious complications. These tools can also ensure that patients receive the right treatments, at the right time, in the right volumes, lessening side effects and improving effectiveness.

mRNA therapeutics are a prime example of complex medicine manufacturing within the UK. The UK's mRNA landscape has expanded since the beginning of the pandemic, highlighted by significant investment from Moderna to produce respiratory disease RNA vaccines locally, as well as Good Manufacturing Practice (GMP) licensing being awarded for two UK facilities to manufacture RNA over the past year. Prioritizing complex medicine manufacturing not only strengthens pandemic preparedness but also fosters a more resilient workforce. The advancements in RNA demonstrate that the UK has the capability to become a world-class hub for pharmaceutical manufacturing.

Complex and innovative medicines manufacturing. It is important for the UK to build and retain a competitive advantage in complex and innovative medicine manufacturing, so that it can capture the full economic benefit of our leadership in life sciences. Manufacturing complex medicines, such as cell and gene therapies and mRNA, requires a highly-skilled workforce and technological capability, meaning the UK has a competitive advantage. It creates well paid jobs

[21] Nelson, M.R. et al. The support of human genetic evidence for approved drug indications. Nature. (2015).

across the UK and high value products for export. By prioritising complex medicines manufacturing, the UK could not only boost trade and exports but also leverage its leadership in life sciences to strengthen its resilience to future pandemics and expand its manufacturing economy.

Medicines manufacturing delivers the largest share of economic activity in the life sciences sector, generating £16.4 billion in GVA for the UK economy each year and supporting 26,000 full-time, high-quality jobs across all parts of the country.[22] A recent report estimated that the UK could attract £15 billion worth of medicines manufacturing investment and double the number of medicines manufacturing employees over the next 10 years if it delivers a supportive policy and operating environment,[23] including a globally competitive R&D tax incentive regime.
It is often a complex process involving many activities – including developing manufacturing processes, testing and quality assurance, regulatory advice, supply chain management, and packaging – which are regularly outsourced to CDMOs. The complexity of medicines and the importance of administering them to patients safely without affecting their efficacy means significant R&D investment is required in the manufacturing process (e.g. to optimise product stability), to improve productivity, increase yields, and reduce emissions. Much if not all of this must be done before a product is ready for the market because medicines must be manufactured for clinical trials. All are essential tasks that are supported by the UK's strong CDMO community, which is also a key asset that can encourage co-location of capital investment from the pharmaceutical industry.

Subsectors

Deep biotech. BIA has coined the term Deep Biotech to refer to the subsector of the biotech industry that encompasses innovative companies powered by engineering biology that address humanity's greatest challenges beyond health, such as environmental pollution and waste, and the climate crisis. These innovative companies are key to the UK's mission to kickstart economic growth while accelerating our path to net zero at the same time. The benefits of this sector are significant, as showcased in the BIA's 2024 Deep Biotech report[24].

Engineering biology and deep biotech can positively transform at least four of the eight growth-driving sectors identified in the industrial strategy green paper, including advanced manufacturing, clean energy industries, defence, and life sciences. Engineering biology is one of the UK's unique strengths and untapped potential, enabling the UK's world-leading sectors to adapt and grow, and seizing opportunities to lead in new sectors, with high-quality, well-paid jobs.

[22] Medicines Manufacturing Industry Partnership. Following the green, high-tech road: A path to UK growth, net zero and health resilience from innovation in medicines manufacturing. (2023).
[23] Medicines Manufacturing Industry Partnership. Following the green, high-tech road: A path to UK growth, net zero and health resilience from innovation in medicines manufacturing. (2023).
[24] BIA: Deep Biotech. (2024).

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5. What are the UK's strengths and capabilities in these sub sectors?

Key points:

- The UK has significant strengths in the above technologies and subsectors whose full potential need to be realised through the industrial strategy and sector plans.
- The UK has a rich history in genomics and significant recent investments in functional genomics, underpinned by a strong academic base and world-leading institutions such as Genomics England and Wellcome Sanger.
- The UK is a leader in techbio and data driven life sciences, underpinned by the UK's wealth of large and unique datasets including the UK Biobank.
- Complex medicine manufacturing capabilities such as for mRNA have rapidly increased in the past years, onshoring manufacturing of novel medicines and creating high value jobs.
- The UK is at the forefront of developing cell and gene therapies, with a unique advantage of academia, industry, government and the NHS working closely together to deliver commercial success.
- The UK is a world-leader in attracting investment into engineering biology, ranking third only behind the US and China, and with significant impact across the environment, materials and chemicals, health, biofuels, biomanufacturing, and agriculture and food.

Genomics and functional genomics. The UK has a rich history in genomics which uniquely positions it to harness the economic, health, and commercial benefits of functional genomics. This is increasingly being merged and expanded with analytics of other biological mechanics such as mRNA and proteins, resulting in multiomics to give a more detailed understanding of health and disease. A strong academic base, combined with institutions such as the Wellcome Sanger Institute and Genomics England put the UK at a strong advantage. Recent investments in functional genomics[25] are a welcome first step, but significant coordination is needed to cement the UK's position. The UK has a world-leading commercial genomics sector, predominantly composed of innovative small and midsize enterprises (SME's). This sector is attracting significant capital, raising £1.85 billion in private investment between 2017 and 2021. Genomics companies also attracted £76.5 million in public R&D grants during the same period.[26] The fast growth and value of this sector is indicated by the projected growth of total market capitalization from £5 billion in 2021 to over £50 billion by 2040.[27]

AI and techbio. The UK is seen as the natural home for techbio technologies given its strong heritage in both life sciences and AI. In addition, the UK is home to a wealth of data assets, that provide a fertile ground for these technologies. Existing capabilities include academic endeavours like the Turing institute and Health data research UK (HDRUK) and world leading data assets like

[25] UKRI: £28.5m in funding for Human Functional Genomics Initiative. (2024).
[26] BIA: Genomics nation 2022: Highlighting future opportunities for the UK genomics sector. (2022).
[27] BIA: Genomics nation 2021: A benchmark of the size and strengths of the UK genomics sector. (2021).

UK Biobank and Genomics England. The UK techbio ecosystem continues to evolve, with companies demonstrating significant growth in research collaborations; many strategic partnerships and licensing deals have been announced in 2024 alone.[28]

Complex and innovative medicine manufacturing. Medicine manufacturing is a rapidly growing industry in the UK, supported by Catapults like the Cell and Gene Therapy Catapult and the Centre for Process Innovation. These centres enable collaboration among academics, technology providers, and therapy developers, accelerating the path from innovation to manufacturing. Through collaboration, companies can more swiftly overcome challenges and bottlenecks, a strength in which the UK excels. Recently, the UK was the first in the world to approve a CRISPR-based gene-editing therapy for sickle cell and Beta Thalassemia. RoslinCT, based in Edinburgh, will be manufacturing this groundbreaking treatment for both UK and US patients.

During Covid, the UK's capabilities in RNA manufacturing grew. As shown in BIA's mRNA explainer,[29] the technology has come far which is reflected by current infrastructure compared to pre-2019. The UK is home to the RNA Centre of Excellence, hosted by CPI in Darlington. The facility is a GMP licensed manufacturing centre which also operates as a training academy. More recently, eXmoor Pharma Concepts Ltd received their manufacturing license to cover RNA as well as other modalities. Moderna recently announced their investment within the UK for manufacture of mRNA vaccines; this investment clearly highlights how the UK is seen as a world-renowned health manufacturing ecosystem. With the correct government support, the RNA and manufacturing industry can propel innovation-driven growth and create the high-quality, high-value jobs essential for our economy.

Cell and gene therapy. The UK has access to world-leading science coming out of UK academic institutions and well-developed scientific clusters that attract international talent and innovation to develop innovative cell and gene therapies. The UK funding environment presents advantages for cell and gene therapy companies, with significant levels of public investment and grant support, including through Innovate UK. Additionally, the UK has a growing private investor base, with London-based venture capital funds such as Syncona and 4BIO providing substantial private investment into UK cell and gene therapy companies. The UK's attractiveness as a location for clinical trials has been driven by the opportunities for collaboration with the NHS and the role of the MHRA as a world-leading regulator. The Advanced Therapy Treatment Centre (ATTC) Network is a unique advantage for the UK in cell and gene therapies, bringing together government, NHS, industry and academia in a powerful and synergistic way to support clinical trials and commercial delivery. This is supported by a strong base in manufacturing of cell and gene therapies that have been developed significantly over the past 5 years.

[28] BIA: TechBio 2024: UK leads innovation frontier. (2024).
[29] BIA: mRNA Revolution: A new generation of medicine. (2024).

Engineering biology & deep biotech. The UK is a world leader in engineering biology R&D. It ranks fifth for the number of engineering biology research publications[30] and fourth for the impact of its engineering biology research. Added to this, the UK has a burgeoning start-up and SME base. The UK is leading Europe in the number of biotech startups and funding for those companies over 2017 to 2022. UK engineering biology firms have fundraised over £5.2 billion between 2017 to 2022[31] The UK ranks third globally in total private investment in engineering biology between 2017 to 2022, only behind the US and China. Around 1,162 engineering biology companies exist in the UK across the breadth of engineering biology applications in various sectors. Detailed applications and innovative companies in those areas in BIA's submission for the House of Lords Science & Technology Committee's inquiry into engineering biology.[32]

The potential of engineering biology to help us design targeted cures for untreatable diseases, reach our net zero and sustainability goals, and to create a truly sustainable bioeconomy, is enormous. Its cross-cutting nature means that it can provide solutions that support as many as 10 out of 17 Sustainable Development Goals (SDGs). It is estimated that more than half of the economic impact from applications of biotechnology overall will lie outside healthcare, with the most significant proportion being in agriculture, aquaculture and food ($0.8–1.2 trillion globally by 2030–40), followed by consumer products and services ($0.2–0.7 trillion globally by 2030–40) and materials and energy production ($0.2–0.3 trillion globally by 2030–40)'. The impact of many non-health applications of biotechnology will, in addition, ultimately have a positive impact on the life sciences sector, for example by reducing healthcare costs due to decreased air pollution, expanding the total economic and social value even further. In 2014, the bioeconomy overall was estimated to contribute £220 billion GVA to the UK economy and supporting over five million jobs.[33] Employment growth in the wider UK industrial biotechnology sector has outpaced national averages, increasing by more than 10% per year, with median earnings around £20,000 above the national average.[34]

Health. The positive impact of deploying advances in engineering biology has been demonstrated in the UK's thriving health life sciences sector. The use of engineering biology enables many of the technologies described above, including cell and gene therapies and mRNA, which are being developed by UK companies.

Agriculture & food. The UK is home to cutting edge companies like Tropic Biosciences, Multus Biotechnology, Hoxton Farms and moa Technology that are aiming to safeguard food security as the climate crisis continues to impact global agriculture. Underlying these innovative companies is a strong academic base with world famous institutions including the Cellular Agriculture Manufacturing Hub, Bezos Centre for Sustainable Protein, National Alternative Protein Innovation

[30] DSIT: National vision for engineering biology. (2023).
[31] DSIT: National vision for engineering biology. (2023).
[32] BIA: House of Lords Science & Technology Committee inquietly into engineering biology. (2024).
[33] Industrial biotechnology: Strategic roadmap for standards and regulations (2020).
[34] IBLF: Growing the UK Industrial Biotechnology Base.

Centre, John Innes Centre, and the Earlham Biofoundry. The UK's vibrant sustainable protein ecosystem emerged from existing strengths in genomics, stem cell biology, mycology, food science, tissue engineering and crop breeding[35]. The recent Genetic Technology (Precision Breeding) Act 2023 was a step forward in making the UK a leader in agritech, but this must be followed on with the enabling secondary legislation so that UK research can begin to benefit from this modernised legislation.

Materials & chemicals. The UK is home to companies operating at the cutting edge of the novel materials and chemical industries such as Colorifix, finalist of the Earthshot Prize 2023, Morden Synthesis and Solena Materials. These companies are supported by good innovation infrastructure for early-stage R&D[36], and the availability of grants for financial support[37]. The UK's strong research base means that there is access to a skilled workforce and the possibility of doing joint R&D with reputable institutions[38]. For example, the UK is home to the first of its kind[39] Hub for Biotechnology in the Built Environment, which aims to revolutionise the construction industry by using incorporating living materials.

Biofuels & Hydrogen, Environment & CO2 capture. UK companies like CyanoCapture, Epoch Biodesign, Phase Biolabs are working to capture and recycle carbon from hard to decarbonise sectors.

Biomanufacturing. Engineering biology processes can make the UK manufacturing sector cleaner and greener. Research at institutions like the Manchester Institute of Biotechnology are advancing the UK's strategic growth in biomanufacturing, with a focus on pharmaceuticals, high-value chemicals, advanced materials, and next-generation biofuels. The UK is home to regional clusters of excellence such as the Tees Valley biomanufacturing hub which contains the Centre for Process Innovation's (CPI) National Biologics Manufacturing Centre, Teesside University's National Horizons Centre and FujiFilm Diosynth's microbial fermentation manufacturing facility in Billingham.

[35] GFI Europe: Sustainable proteins in the United Kingdom: An ecosystem review. (2023).
[36] Innovation Research Caucus: Mapping the innovation and commercialisation infrastructure for non-health application of engineering biology in the UK. (2024).
[37] Innovation Research Caucus: Mapping the innovation and commercialisation infrastructure for non-health application of engineering biology in the UK. (2024).
[38] Innovation Research Caucus: Mapping the innovation and commercialisation infrastructure for non-health application of engineering biology in the UK. (2024).
[39] North East Times: Newcastle and Northumbria universities combine for £8 million world-first building research hub. (2019).

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6. What are the key enablers and barriers to growth in these sub sectors and how could the UK government address them?

Key points:

- Precision medicines, techbio and genomics need significant investment, an innovation friendly approach to regulation, a refreshed approach to adoption of innovation in the NHS, and access to health data.
- Complex medicine manufacturing needs continuous funding streams, a "single front door" approach to account management, a supportive infrastructure to deliver clinical trials at speed and scale, and an upskilled and reskilled workforce.
- For cell and gene therapies to benefit patients in the UK, we need alternative approaches to reimbursement for cell and gene therapies, including innovative payment models, to ensure timely patient access to treatments, as well as access to a skilled workforce.
- For the engineering biology and deep biotech SME base to start and scale in the UK, we need pro-innovation regulation, access to affordable scale up infrastructure, and access to early-stage public funding and scale-up finance.

Precision medicines, techbio, and genomics. A joined-up approach to supporting these technologies would not only help support these burgeoning technologies to flourish, but also align with the NHS 10-year plan, which seeks to shift to prevention and tech-enabled care. Significant investment is required by AI, techbio and functional genomics platforms. This is because the training of large-scale machine learning, large language models and generative AI models is an extremely expensive exercise that needs to be repeated frequently, putting underfunded UK businesses at a major disadvantage compared to global competitors.

An innovation friendly approach to regulation is another key enabler for AI, techbio and functional genomics platforms. Currently, the UK has adopted a flexible approach to regulating AI, this is important within the life sciences as it allows AI to be applied in low-risk settings with proportional regulation. However, as technology is adopted more within the NHS, a clear agile framework for regulating technology in healthcare is needed, so that innovations can be developed and brought to patients in a safe but competitive manner.

The reimbursement options currently available do not support the adoption of many precision healthcare technologies. This is in part because the current health system incentivises treating sickness with ‘one size fits all’ drugs or therapies, rather than early diagnosis or targeted therapies. A refreshed approach to adoption of innovation in the NHS is needed. This would see aligned incentives that route funds to innovations that bring down the overall cost of healthcare. This would include fiscal frameworks that evaluate the full costs and benefits of preventative-health interventions and account for long term impacts of interventions. Dedicated funding for precision

and preventative health technologies would better support companies that align with the NHS 10-year plan.[40]

Access to health data is another key area where government intervention is needed. Multiple different data custodians now operate under different governance mechanisms, with different processes, data standards and technical environments. This trend of fragmenting health data in multiple, siloed, Secure Data Environments (SDEs) which lack unifying data representation and quality standards prevents research and innovation. Health data should be accessed by streamlined and standardised access processes, which are clear and transparent. secured in SDEs which are technically flexible and provide IP protection to innovators, and standardised and interoperable, where appropriate, to support interconnected or federated data analysis.

The recommendations of the Sudlow review need to be implemented in close collaboration with innovators in the life science sector.

Complex medicine manufacturing. Manufacturing medicines within the UK has considerable barriers when compared to other countries such as the US, Singapore and Ireland. Funding in advanced therapy fields, such as cell and gene therapy manufacturing, delivers a high economic return and should therefore be readily accessible to companies leading in innovative manufacturing. Companies are more likely to invest in countries with higher and more regular funding streams which are accessible to a wider pool of applicants. Implementing a "single front door" approach to account management encompassing land availability, planning permissions, and energy grid connections would make the UK a more compelling choice for investors looking to establish manufacturing operations. Creating a supportive infrastructure to enable collaboration between academia and industry will lead to increasing the UKs attractiveness for clinical trials, which is essential for positioning the UK as a leader in advanced therapy manufacturing. Upskilling and reskilling are essential to address the increase in demand of therapies. Lastly, the unpredictability of supply chains drives up cost of manufacturing, which in turn decreases the value of products.

CDMO's play a critical role within the sector. They enable therapy developers to outsource manufacturing without needing to invest in capital and gain access to GMP and regulatory experts. For CDMOs to be successful, there needs to be funding available to support the development of product through the manufacturing pipeline. As demand for therapies increases, infrastructure must be in place to manufacture the products to ensure UK patients do not miss out on life saving interventions.

Cell and gene therapies. Cell and gene therapies face particular challenges within the evaluation and reimbursement system owing to their high up-front cost and uncertainty with regard to long-

[40] Tony Blair Institute for Global Change: Prosperity through health: The macroeconomic case for investing in preventative health care in the UK. (2024).

term outcomes. However, these treatments have enormous potential to transform patient outcomes, and the health system recognises the full value of these treatments so that patients in the NHS can benefit. We are now seeing increasing numbers of treatments being made available, including in the UK, with the NHS starting to deliver these potentially life-saving therapies to patients with blood cancer as well as some rare genetic diseases. As more cell and gene therapies become available, it is important that the NHS, NICE and other key stakeholders work collaboratively with industry to ensure UK patients are among the first to benefit. Alternative approaches to reimbursement for cell and gene therapies, including innovative payment models, can help to ensure timely patient access to treatments while balancing risks and benefits between the NHS and industry.[41]

In addition, the level of employment in the UK cell and gene therapy sector has grown significantly in recent years, with the Cell and Gene Therapy Catapult's latest Skills Demand Report[42] identifying over 6,232 roles in 2023, approximately double the number in 2019. The report found that companies are expecting overall employment to grow by 63% over the next five years, reaching over 10,000 by 2028. Targeted support from Government is required to ensure that the continued growth of the sector is not restricted by the unavailability of a skilled workforce.

Engineering biology. The National Vision for Engineering Biology was received well by industry, and it is important that Government continue to work closely with industry to implement it, and uphold and expand its spending commitment. The Vision provides a strong signal of intent from Government, showing the sector that it is a priority. This sends a powerful message to global investors, too.

The priority areas to focus and deliver on to accelerate deep biotech in the UK are infrastructure, regulation, and finance. Significant progress must be made in these areas in the next five years to ensure innovative companies can succeed and future start-ups are welcomed by a supportive, globally competitive UK ecosystem in which they can thrive.

We need regulators to have a pro-innovation, collaborative mindset and to be resourced appropriately, both in terms of funding and knowledge, to be able to horizon scan and deliver effective regulation so engineering biology companies can bring their novel products to market. Working together, with public research funders and with industry, regulators must ensure that where regulation is required for innovative products, it is provided, and where it is not, it is clear that companies can commercialise their products safe in the knowledge that they are acting within UK law. On finance, engineering biology companies can struggle to receive the funding necessary to start and scale up in the UK. The government must continue to unlock capital that is key to delivering long-term strength in the UK venture financing ecosystem that most engineering biology companies rely on. We need proof-of-concept funding from Innovate UK and an

[41] BIA: Ensuring patient access to cell and gene therapies: The case for an innovative payment model. (2021).
[42] Cell and Gene Therapy Catapult: Skills survey. (2024).

internationally competitive and efficient R&D tax relief regime benefitting deep biotech companies. On infrastructure, we need better accessibility, affordability and availability of scale-up infrastructure and specialist equipment.

Business Environment

7. **What are the most significant barriers to investment? Do they vary across the growth-driving sectors? What evidence can you share to illustrate this?**

Key points:

- The UK life sciences sector is world leading but has a number of characteristics that can be barriers to investment.
- The sector is capital intensive and timelines to commercialisation are often very long. Pre-revenue businesses must raise multiple, successive rounds of venture capital, and are thus reliant on broad, deep and pro-risk capital markets.
- The UK has fewer established life sciences investors compared to the US or European competitors, especially in deep biotech, where the investor pool is smaller.
- A holistic view of the economic landscape is needed to address these barriers including, access to finance (including R&D tax relief), skills, the research pipeline, and the UK's regulatory framework.

The life sciences and biotech sector – despite its world-leading strength – faces unique challenges, and the life sciences business model has unique characteristics that present barriers to investment, that must be considered by policy makers when designing an industrial strategy and also when determining the economic benefits that can be gained.

Due to the long R&D timelines, high capital requirements, and cutting-edge nature of life sciences and biotech, the sector is more dependent on venture capital than almost all others. Pre-revenue businesses must raise multiple, successive rounds of venture capital, with the total amount needed to develop a single new medicine regularly exceeding £1 billion.

In addition to the high level of capital required, R&D remains a risky and uncertain process, with most projects failing due to the complexity of cutting-edge science. Using drug development as an example fewer than 14% of all drugs in clinical trials making it through regulatory approval, with the process taking 10-15 years in its entirety.

Moreover, investing in life sciences is a highly specialised activity, and the UK has relatively few established investors compared to the US or even our European competitors. This is even more pronounced for subsectors such as deep biotech where the investor pool is smaller and more fragmented.

Sustained industrial strategy support from government is therefore essential to maintain momentum, and further private investment can be attracted via:

Access to finance. Ensuring start-ups and scale-ups have access to finance at all stages of development creates a stable economic landscape that reassures investors that the market is supported, and that companies are able to access finance at each stage of development. This includes access to diverse finance for high-risk, high-reward projects and for all phases of R&D, from academic research through to all stages of its translation and commercialisation into products and processes that benefit people. Alongside government grants, and private investment, a supportive tax system, including R&D tax relief, is crucial to this.

Thriving talent & skills pipeline. Academia and other education providers in the UK need the right support to nurture talent and develop skills. To provide the right skills and talent to companies and the wider sciences ecosystem, education, training, reskilling and upskilling need to be continuously supported and well-funded. In addition, knowledge exchange and collaboration across organisations and borders is fostered and a supportive immigration framework in place. Industry also has an important role to play in upskilling the workforce and the life sciences sector is committed to this.

Strong pipeline of research translation. A deeply embedded successful mechanism to translate research into products and processes of economic and societal value. This includes diverse and abundant public and private funding for start-ups and scale-ups at all stages of development on the one hand and growing the leadership and entrepreneurial skills needed to build on and progress bold ideas and companies on the other. Access to infrastructure is also essential, with both cost-accessible pilot (early-stage) and scale-up facilities, and the availability of specialist equipment and high-throughput lab equipment, of particular importance.

A supportive regulatory and legal environment. The UK maintains and builds on its robust and science-led regulatory regime. Its regulatory framework is agile and responsive, allowing innovation to flourish while maintaining the confidence of government, innovators and the public. However, science is global, and regulation operates within that global context too. The UK needs strong regulators which not only lead the conversation nationally but also internationally. Similarly, strong intellectual property rights are vital for life sciences companies to be able to attract investment to innovate and grow.

UK BioIndustry Association

Business Environment – People and Skills

8. **Where you identified barriers in response to Question 7 which relate to people and skills (including issues such as delivery of employment support, careers, and skills provision), what UK government policy solutions could best address these?**

Key points:

- Skills and talent are key barriers to growth in UK life sciences, and the current skills system is complex and misaligned with the Industrial Strategy and key growth sectors.
- The system needs to be simplified using data-driven decision-making and better alignment across schools, further education, and higher education to attract industry investment.
- Over 50% of the life sciences workforce holds advanced technical qualifications, making funding for relevant qualifications and industry engagement essential to meet workforce demands.
- The complexity of funding systems like the Growth and Skills Fund limits SME participation. More funding and coordination are needed to enhance SME engagement and industry investment in training.
- A simple and efficient visa system to lower recruitment barriers for start-ups and scale-ups is essential for their success.

Skills and talent are a complex issue and significant barrier to growth for UK life sciences. There are a number of policy solutions and barriers to be addressed that will allow the UK to capitalise on its strengths in life sciences.

Skills England. The skills system is complex across the UK, and devolution exacerbates this complexity. The current system is not aligned to the industrial strategy, migration policies, or sectors that are key to UK growth. We welcome the creation of Skills England, which should address this using data driven decision making. Improvements and alignment need to be delivered across schools, further education, and higher education institutions. Making the system simpler for businesses to engage with is also a key step for attracting industry investment.

Qualifications. Over 50% of the life sciences workforce are in highly technical roles requiring advanced qualifications, with 70% holding degree or equivalent qualifications – twice national average (from the new 2035 Futures Skills analysis). Funding of PhDs, CDTs and other technical qualifications is vitally important, as is industry engagement to address the current employability and workforce demands.

Growth and skills fund. The current complexity of the system prevents many SMEs from benefitting from the fund. In addition to the system and process complexity, it also needs someone to manage it, which can be tricky when headcount is limited. More funding is needed for

co-ordination of SMEs – like the Cell and gene Therapy Catapult's programme, Advanced Therapies Apprenticeship Community – which has increased SME engagement in existing programmes, and increased industry investment in training.

Immigration. Life sciences is a global industry, and innovation requires new ideas and diverse points of view. Most companies employ a majority non-UK workforce to get the skills and creativity they need to compete in a global marketplace. Therefore, creating a simple and efficient visa system to lower recruitment barriers for start-ups and scale-ups is essential for their success.

The UK visa system is complex and lengthy, creating unnecessary costs for the companies. Changes are required to make visa system to make it easier and quicker to navigate for firms looking to recruit the best international talent. The criteria for the Global Talent visa (GTV) should be clarified to ensure that UK-based R&D-intensive businesses, including early-stage biotechs, are eligible. The Government should also consider introducing a version of the Tech Nation GTV for the life sciences sector.

9. What more could be done to achieve a step change in employer investment in training in the growth-driving sectors?

Key points:

- Many businesses are unaware of funding opportunities, and in many cases the systems are geared toward more academic experience.
- Stronger partnerships between research councils and industry, with joint investments, would help overcome funding barriers and improve workforce skills.
- Investment in AI, techbio, and genomics platforms requires attracting more interdisciplinary tech talent, with alignment between AI skills hubs and life sciences.
- Skill gaps remain across the life science, but particular attention is needed with regard to regulatory roles, entrepreneurial and business acumen, and support for diversity and inclusion

Many schemes that address the lack of employer investment in training are primarily designed with large companies in mind. The schemes can be harder to access for smaller companies with less resource. To combat this, specific funding is needed for SMEs, as well a targeted support with the specific intention of catering for these smaller companies.

Collaborative training partnerships. There is a distinct lack of awareness about what funding is available for businesses as opposed to academia. UKRI's Future Leadership Fellowship is a good example of this issue, with the scheme attracting many academic applications and very few business ones. This is, in many cases, due to the fact that the system is systems primarily set up for those with experience writing academic grants, publishing papers, and working in a university setting. Collaborative training partnerships would be a good way to combat this, with 50:50

investment from research councils and industry. Also providing more information to businesses about investment returns would help boost investment. Innovate UK has made some progress in this regard, but more work is needed.

UKRI's Medicines Manufacturing Skills: Centre of Excellence Hub. Advanced manufacturing and the development of medicines through novel modalities, such as gene therapies and mRNA, requires both an increase in the volume of new talent entering the sector, and the upskilling of existing talent. Investment into UKRI's Medicines Manufacturing Skills: Centre of Excellence Hub should be increased, and industry should be encouraged to match this investment where possible.

Apprenticeships. Apprenticeships and technical education reforms have revolutionised alternative career pathways into life sciences. Trailblazer engagement in standard development for larger organisations has satisfied the requirements for our sector, but consultation with SMEs remains vital to ensuring 75% of the sector are not excluded from these programs. Qualifications must be retained within higher and degree apprenticeships to ensure parity with a sector reliant on graduate entry and removal would limit progression through the sector. Careful consideration should be given to funding of Level 7 apprenticeships in particular areas such as Regulatory Affairs, Bioinformatics and Research Scientist which provide a talent pipeline for new entrants with integrated skills to the sector.

Attracting tech talent. Investment in major AI, techbio, and functional genomics platforms requires significant new computational skills and interdisciplinary talent able to work across scientific, engineering and technology areas. This is currently the most recruited for area in the sector (according to an analysis of job adverts). Attracting tech talent to work in the sector will be key, as well as aligning AI skills hubs with life sciences, and the establishment of CDT funding cross faculties.

Increase of regulatory professionals. Due to the complex and evolving landscape of data, manufacturing, technology, and the general speed of innovation, regulatory professionals are in critical demand in the UK life sciences sector. Steps need to be taken where possible to address this skills gap.

Commercialisation. There are not enough people or leaders with the entrepreneurial skills and understanding of the investment landscape required to scale companies in the UK. As such, improvements are needed in leadership and entrepreneurial training and accelerators.

Diversity, equity, and inclusion. Life Sciences lack diversity, particularly in leadership, and this can have negative repercussions with regard to attracting talent. Alternative career pathways – such as apprenticeships – are needed, as well as routes back into the sector for returners and further support for leadership development.

UK BioIndustry Association

Business Environment – Innovation

10. Where you identified barriers in response to Question 7 which relate to RDI and technology adoption and diffusion, what policy solutions could best address these?

Key points:

- New clinical trial legislation should be prioritised to ensure timely patient access to innovative medicines, and brought to parliament by the end of 2024.
- Further action is needed regarding the O'Shaughnessy review recommendations, particularly with respect to participant availability and start-up delays.
- The Innovative Licensing and Access Pathway (ILAP) should be relaunched to take into account the evolving needs of the UK innovative life sciences and biotech industry.
- A refreshed approach to NHS innovation adoption is needed, with better funding for precision and preventative health technologies to align with the NHS's 10-year plan.
- The uptake of engineering biology and deep biotech solutions in existing industries needs to be incentivized through preferred procurement routes, tax incentives, net zero goals, and fit-for-purpose regulation.

Clinical Trials Legislation. The BIA has highlighted that prioritisation of new legislation for clinical trials is important to ensure the UK remains an attractive destination for international clinical trials, enabling patient access to innovative medicines sooner.

However, there is no clear timeline for when the statutory instrument will be laid in Parliament. The government published in March 2023 its response[43] to a public consultation on an ambitious legislative reform of the UK clinical trials regulatory framework to which the BIA responded. The BIA calls on Government to bring the required statutory instrument to parliament for approval by the end of 2024.

O'Shaughnessy recommendations. The Lord O'Shaughnessy independent review,[44] published in May 2023, set out 27 recommendations to improve the environment for commercial clinical trials. Some progress has been made in implementing these recommendations, but it is necessary to maintain momentum so that outstanding issues around the availability of trial participants and NHS site start up are addressed.

NHS adoption of innovation. The BIA welcomed the Innovative Licensing and Access Pathway (ILAP) since its launch in 2021. This is a unique initiative which aims to accelerate the time to patient access for transformative new medicines.

[43] MHRA: Consultation on proposals for legislative changes for clinical trials. (2023).
[44] DHSC, OLS, DSIT: Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report. (2023).

The BIA calls on Government to relaunch its ILAP offer taking account of the evolving needs of the UK innovative life sciences and biotech industry. In our members' view ILAP provides a single integrated platform where the company can work collaboratively with the MHRA, UK health technology assessment bodies and the NHS from the early stages of clinical development, which is a key draw that other comparable schemes in the EU and the US do not offer.

In addition, the reimbursement options currently available do not support the adoption of many precision healthcare technologies. This is due in part to the fact that the current health system incentivises treating sickness with 'one size fits all' drugs or therapies, rather than early diagnosis or targeted therapies. A refreshed approach to adoption of innovation in the NHS is needed. This would see aligned incentives that route funds to innovations that bring down the overall cost of healthcare. This would include fiscal frameworks that evaluate the full costs and benefits of preventative-health interventions and account for long term impacts of interventions. Dedicated funding for precision and preventative health technologies would better support companies that align with the NHS 10-year plan.

Engineering biology & deep biotech. The social, economic and environmental impact of engineering biology and deep biotech is huge, but many challenges remain to its adoption across the UK's growth-driving sectors and markets, Government policy has a critical role to play in ensuring these can be overcome, by setting incentives for existing and established industries to adopt biosolutions, and through preferred procurement routes, tax incentives, or net zero goals that support the uptake of deep biotech. In addition, regulations need to be made fit-for-purpose to allow novel deep biotech products to reach the market.

11. What are the barriers to R&D commercialisation that the UK government should be considering?

Key points:

- The UK life sciences sector leads in R&D investment but faces challenges when translating academic discoveries into industry and scaling up innovative companies.
- Improving the start-up and spin-out capability of the UK will require increased finance and business training for entrepreneurs and increased Innovate UK and Biomedical Catalyst funding.
- R&D commercialisation can be accelerated by removing barriers to collaboration between academia and industry.
- The UK lacks venture capital funds at the scale required to support the growth of innovative businesses, despite high levels of foreign investment.
- This market failure is largely driven by risk aversion in the investor base and needs to be addressed.

The UK's life sciences sector is among the most research, development and innovation intensive sectors in the UK, consistently investing more into R&D than any other sector. Commercialisation is the route through which the UK realises the large economic, social, environmental and health benefits of our world-leading R&D and innovation.

The most significant problems for commercialising discoveries in UK life sciences are found in the early-stage translation of ideas from academia into industry on the one hand, and scaling up and growing innovative companies in the UK through access to scale-up UK finance, on the other. The former is linked to resource constraints in both academia and industry, especially SMEs; lengthy bureaucratic processes; and difficulties around ownership of intellectual property. The latter is linked to limited availability of UK-based scale-up finance, including venture capital and institutional investment for life sciences companies.

Academia to industry

Start-ups and spin-outs are an important route for commercialisation of R&D, as evidenced by the recent successes of companies such as Quell Therapeutics, Kymab, Oxford Nanopore, Immunocore, Arecor, and Colorifix. To ensure continued commercialisation of R&D, including that conducted in academia, we need to increase finance and business training in post-graduate courses to equip a new generation of entrepreneurs with the skills they need to start and grow businesses.

- We need to expand the budget of Innovate UK and the Biomedical Catalyst to provide more innovation support to early-stage companies and spinouts in the life sciences sector and to strategically important technologies, including engineering biology.
- We need to standardise terms and conditions for technology transfer across the UK, accelerate response times for deal making, and explore ways for Technology Transfer Offices (TTOs) to become matrixed to facilitate greater sharing of expertise across the TTO community. This includes easing the often contentious and complex negotiations between TTOs and VCs.
- We need to implement the recommendations of the independent review of UK university spinouts,[45] which includes increased UKRI funding for the proof-of-concept stage.

Another way in which R&D can be commercialised is as a result of academia-industry collaborations. Removing barriers to such collaboration will increase R&D commercialisation. Some of the barriers to academia-industry collaborations are caused by disagreements over IP; lengthy, time-consuming bureaucratic processes involved in collaboration agreements; difficulties in identifying the right partners; and lack of resources, which acts as a significant inhibitor especially for SMEs.[46]

[45] DSIT, HMT: Government response: Independent review of university spin-outs. (2023).
[46] NCUB and CBR: The changing state of business-university interactions in the UK. (2022).

Scaling up and growing innovation

The UK has fewer venture capital funds at the scale required to support the growth of innovative businesses than many of its peers, due in part to UK pension funds having a significantly lower allocation to private equity and infrastructure assets. As a result, investment is largely coming from overseas investors, which is a vulnerability for our domestic sector as it creates an incentive to move closer to where the investors are (usually the US) and means value is not being captured and recycled in the UK.

As the British Business Bank showed in their latest Equity Tracker report,[47] the UK still under-invests in life sciences venture capital when compared to the US, despite being a global leader in the sector. The British Business Bank's data demonstrates that UK investors do not want to invest in UK life sciences, and yet the sector attracts a disproportionate number of US investors. This clear market failure is driven by risk aversion in the UK investor base, with the life sciences – incorrectly – being seen as one of the riskiest sectors to invest in. Strong government leadership is needed to change this behaviour, and to address the very unique market failure for life sciences in particular.

Modern life sciences R&D is complex and highly specialised. Most of it is conducted by a network of specialist SMEs and start-ups who are the lifeblood of the sector, producing the medicines of tomorrow. For these companies to bring innovations to market, barriers to scale-up finance need to be removed.

Business Environment – Data

13. What challenges or barriers to sharing or accessing data could the UK government remove to help improve business operations and decision making?

Key points:

- The two key barriers to data access are technical challenges and governance.
- To overcome the governance barrier, the access and governance process should be rationalised and harmonised. A national data service would be a key step.
- To overcome technical challenges, government should introduce data standards and accredit and standardise SDEs (secure data environments).

There are two broad areas where life science companies face challenges in accessing health data and government intervention is needed: governance and technical. Both challenges (outlined below) can impact business decision making. For example, there are often no guaranteed timelines for data access approval, and this can take months or years. Projects are delayed, and funding is put at risk due to these uncertainties. Furthermore, even once access to data had been

[47] British Business Bank: Small Business Equity Tracker 2024. (2024).

granted, it can be stored in unworkable environments or the data itself unusable for various quality reasons.

Governance as a barrier to data access. Governance barriers are those associated with the rules of accessing or using data. These may be legal or ethical requirements and are implemented both nationally and locally. While regulation is necessary, it can create a disproportionate barrier to SMEs, which have less financial resource or capacity for this type of work. The government should look to taking up recommendation four of the Sudlow review,[48] which suggests rationalising and harmonising access processes and governance. Setting up a national data service, which guarantees timelines and service through a service agreement, would provide much assurance to life science companies.

Technical barriers to data access. Technical barriers are practical issues that delay or prevent existing data being optimally used. These include problems like non-digital data sources, poor quality or unstandardised data, inaccessible data and incomplete or insufficiently linked data. Data should be collected under the FAIR principles (Findable, Accessible, Interoperable and Reusable) to avoid this. Government should look to introduce data standards where possible and take up recommendation five of the Sudlow review to accredit and standardise SDEs which hold health data. These standards should be introduced following consultation with data users across industry. Giving confidence in the quality of the UK's health data will attract more companies to use UK data rather than moving abroad. Bringing with it opportunities for our health and wealth.

Business Environment – Infrastructure

14. Where you identified barriers in response to Question 7 which relate to planning, infrastructure and transport, what UK government policy solutions could best address these in addition to existing reforms? How can this best support regional growth?

Key points:

- Deep biotech SMEs need better access to, availability and affordability of infrastructure and specialised equipment to enable them to scale.
- Companies need funding support to access pilot and scale-up facilities. A voucher or credit scheme should be trialled to stimulate demand and increase capacity.
- Investment into large-scale infrastructure is essential and must include financing for highly skilled staff.
- The UK must address the infrastructure gaps in medicines manufacturing to compete with the growing demands of advanced therapies.

[48] Sudlow, C. Uniting the UK's health data: A huge opportunity for society. (2024).

- Digitalisation will play a key role and advanced digital infrastructure, and optimisation initiatives should be funded.

Buildings, transport and other traditional infrastructure are critical for life science and biotech companies, and insufficiencies will hold back the sector. However, our answer here regards more specialist infrastructure used by innovative companies.

Deep biotech. Both to start and to reach scale, many deep biotech SMEs need large, costly physical infrastructure or specialist equipment. Existing pilot and scale-up infrastructure, particularly bioprocessing facilities, needs to be made more accessible through informative and financial levers. Smart sharing of existing infrastructure needs to be enabled, and universities and other infrastructure holders should be encouraged and supported to share their facilities and make it easier for companies to enter agreements and negotiate rapid access.

Companies need funding support to access existing pilot and scale up facilities in a cost-accessible way, including for upstream and downstream bioprocessing, and to access specialist equipment, noting that different sectors need different equipment. Funding support is also needed for the continued running of existing facilities and the staff needed to support companies throughout the process. A voucher or credit scheme for companies to spend at vetted facilities should be trialled to support companies, and to stimulate demand and increase capacity in the system of infrastructure providers.

We need to invest in large-scale infrastructure – particularly bioprocessing facilities that are currently lacking – such as large-scale food grade fermentation facilities for cultivated novel foods, and Good Manufacturing Practice facilities for the development of therapeutics based on engineered microorganisms. Such investment must include financing of the highly skilled staff that are essential for the running and maintaining of specialised infrastructure and equipment.

Complex medicines manufacturing. A major issue within medicine manufacturing is the lack of infrastructure readily available. Whilst the UK has a flourishing contract development and manufacturing organisations (CDMO) community, this is not enough to support the upcoming demand of innovative therapies; for example, currently around 11,000 cell therapy doses are produced annually, and it is expected that 160,000 doses will be required annually to ensure eligible patients are treated. The next few years in advanced therapies are critical, and manufacturing space is one of the main bottlenecks. Capital grants programmes, such as the Life Science Innovative Manufacturing Fund, are welcome. We comment further on it in response to the next question.

Digitalisation plays a key role in medicine manufacturing. To be able to reach the required number of doses annually across all innovative therapies, automation and AI driven analytical tools will be required. The government should fund initiatives for advanced digital infrastructure to enable optimized processes, digital twins and secure data storage. Not only does digitalisation aid

towards sustainability goals, it will also grow the economy through increasing return on investment for UK manufactured products.

15. How can investment into infrastructure support the Industrial Strategy? What can the UK government do to better support this and facilitate co-investment? How does this differ across infrastructure classes?

Key points:

- Infrastructure investment in the life sciences is essential, as the UK cannot meet the manufacturing demands of a healthy workforce.
- CDMOs and in-house manufacturing can help prevent production bottlenecks and warrant investment.
- To unlock the growth potential of the life sciences, investment is needed beyond infrastructure and into R&D companies.
- The Mansion House Compact, British Growth Partnership and National Wealth Fund are positive steps, but work is needed to ensure the unlocked funds are channelled into the life sciences.

Infrastructure within the life sciences sector is essential, especially as we adopt more advanced techniques for medicine manufacturing. As manufacturing processes evolve to meet Net Zero goals, facility design and requirements are also changing. Currently, the UK lacks a sufficient number of specialized facilities to meet the demands for a healthy, resilient workforce.

Capital grants programmes, such as the Life Science Innovative Manufacturing Fund, are welcome to incentivise investment into commercial stage manufacturing infrastructure. However, it should be noted that for funding in this capacity to be successful, the grants must be open to SMEs as well as large companies. The criteria of the grants should be clear from the beginning and should encompass expenditure on equipment as well as buildings. We also note that the £520 million Fund was due to run for five years from 2025 and £70 million has been allocated to the 2025-26 financial year. It is important that the expected five-year lifespan is maintained and the remaining funds are not backloaded to the end of the funding period.

Contract Development and Manufacturing Organisations (CDMOs) also play a vital role in providing manufacturing infrastructure, including in R&D phases of company growth. The R&D tax relief regime should enable these companies to claim relief for R&D they do on behalf of non-UK clients (UK clients should be able to claim themselves and double-claiming should not be permitted). This would incentivise CDMO infrastructure investment in the UK and attract investment from overseas clients, whilst spillover benefits of UK-based R&D undertaken by the CDMOs would be captured by our economy. We are currently in conversation with the Treasury on this matter.

However, as important as infrastructure investment is, to fully unlock the potential of the sector and drive economic growth, investment is needed beyond infrastructure and into R&D-intensive start-ups and scale-ups themselves. We welcome the Chancellor's focus on this in her recent Mansion House speech.

The Mansion House Compact in 2023 was an enormous step forward for the UK's financial services industry and has given hope to start-ups and scale-ups that the pensions industry is ready to engage with them and invest in their growth, in a way that foreign investors and pension funds already do. We believe there is appetite among some progressive pension funds to invest into UK life sciences and they may develop their own solutions to enable them to gain exposure. However, there will be a longer tail of potentially interested but much less motivated pensions that will continue to argue that regulations or systems prevent them from participating in the innovation economy and supporting growth. What's more, it is essential that the unlocked funds are successfully driven to the life sciences and other innovative, growth-driving sectors.

The British Business Bank, and its subsidiary British Patient Capital, have become a critical cornerstone of the UK venture ecosystem and will be instrumental in Labour's growth mission and industrial strategy. Following the recent progress with Mansion House and the ongoing Pension Review, the scale of equity investment needs to be the focus moving forward. As the pension reforms may take multiple years to result in the substantial extra investment our sector needs, funding from the British Business Bank is a vital source of capital for innovative UK businesses that are scaling now and want to stay in the UK.

The recently announced British Growth Partnership, as well as the National Wealth Fund, are key steps in the right direction, but the sector-specific characteristics and capital hungry nature of the life sciences will require a more targeted approach, and the British Business Bank should work with our industry to ensure this is delivered.

Business Environment – Competition

19. How can regulatory and competition institutions best drive market dynamism to boost economic activity and growth?

Regulatory and competition institutions need to act as enablers of economic growth and innovation, especially with regard to their interactions with start-ups and scale-ups. This should be in their objectives.

National security is an area of particularly fine balance for innovative life sciences and biotech. The National Security and Investment (NSI) regime requires certain types of investments into companies, including those working on synthetic (engineering) biology and AI, to have proposed investments cleared by the Government ahead of completion to ensure there is no risk to national security. The life sciences and biotech sector rely heavily on private investment, including from abroad, and on IP to secure such investment, and are powered by engineering or synthetic

biology. To ensure continued growth and success of the life sciences sector, it is critical that regulatory and competition institutions, including the NSI regime, operates not to impose an unnecessarily high burden on start-ups and scale-ups, and the sector's emerging technologies, but operate efficiently without hindering critical investment. This can be achieved with clear and predictable rules, developed through industry engagement, and efficient operational delivery.

Business Environment – Regulation

20. Do you have suggestions on where regulation can be reformed or introduced to encourage growth and innovation, including addressing any barriers you identified in Question 7?

Key points:

- Clearer, more accessible regulatory pathways are needed for deep biotech innovation, alongside updated legislation and better signposting.
- Engineering biology applications are subject to multiple regulators. They must be better resourced in terms of both funding and knowledge. This will enable them to respond appropriately to deep biotech innovation and provide timely and consistent approvals and guidance.
- Strengthening collaboration between regulators and industry is essential, with more proactive engagement, regulatory sandboxes, and continued support for initiatives like the Engineering Biology Sandbox Fund.
- A strong and supportive UK regulatory environment is needed that is globally competitive and attractive.
- The MHRA must be adequately resourced to ensure quality service and financial sustainability and enable predictable review timelines for medicines and clinical trial applications.

Deep biotech regulation

The industrial strategy green paper rightly identifies that the regulatory environment in which the growth-driving sectors operate will be an important determinant of their success, and that regulation should support emerging sectors to grow, while enabling existing sectors to modernise and evolve. To enable deep biotech – and engineering biology as a foundational technology – to empower the UK's growth-driving sectors, it is imperative that regulatory barriers are addressed.

Improve regulatory clarity for deep biotech products and processes. While for some companies the regulatory pathway and/or regulator is clear, this is not the case across engineering biology applications. Innovation in engineering biology is outpacing existing regulatory frameworks, creating significant gaps. Working together with public research funders and with industry, regulators must ensure that where regulation is required for innovative products it is

provided, and where it is not, it is clear that companies can commercialise their products and reach market safe in the knowledge that they are acting within UK law. This includes:

1. Publishing an overview of regulatory bodies and pathways for engineering biology-based products, including information on how innovative engineering biology companies can approach regulators and who to approach, through clear signposting and by providing guidance (including case studies) where none exists.
2. Reviewing and updating relevant legislation and regulation to make it fit-for-purpose and future-proof to allow for engineering biology innovations to safely reach market in the UK.

Resource UK regulators appropriately, both in terms of funding and knowledge. We need regulators to have a pro-innovation, collaborative mindset and to be resourced appropriately, to be able to horizon scan and deliver effective regulation and guidance to deep biotech companies. Regulators must have adequate funding and knowledge to be able to stay ahead of the curve, be consistent in their delivery, and provide clear and timely approvals processes, information, and guidance to companies. Regulators must be resourced to build an adequate knowledge base to be able to appropriately and quickly understand and, where relevant, regulate engineering biology innovations. Creating a strong regulatory knowledge base should be done with support from, and in close collaboration with, industry partners, and include early and informal engagement with start-ups and SMEs.

Strengthen regulator-industry relationships to build future-proof, enabling regulation to bring novel products to market. Regulators need to increase active and early engagement with early-stage companies and SMEs, prior to applications being filed. This can be materialised through workshops and working groups, facilitated and informal meet ups with companies of similar products and relevant regulators, proactive engagement with industry through the Engineering Biology Regulator's Network (EBRN), and through regulatory sandboxes in areas of most pressing need. The Engineering Biology Sandbox Fund must be continued and built upon to accelerate pro-innovation regulatory reform and encourage deep biotech innovation and investment in the long-term. Strong regulator-industry relationships will further support the regulatory knowledge base.

Deploy the Regulatory Innovation Office (RIO) to foster a joined-up approach to Deep Biotech regulation. The new Regulatory Innovation Office (RIO) needs to rapidly deliver, and at scale, on its 'capability' workstream to build capability across the whole regulatory system so it can respond to engineering biology as an emerging technology. This includes using its function to improve regulatory clarity for deep biotech and build up UK regulator's knowledge base. The RIO needs to work closely with the Regulatory Horizons Council (RHC) and the Engineering Biology Regulator's Network (EBRN) so not to duplicate efforts but make targeted interventions to drive pro-innovation regulation in deep biotech. The RIO needs to develop advice for regulatory bodies to assess the most pressing regulatory gaps and needs to improve regulatory clarity for deep

biotech companies. The regulatory bodies to engage with include, but are not limited to the Office for Product Safety and Standards (OPSS), Health and Safety Executive (HSE), Department of Environment, Food, and Rural Affairs (DEFRA), Food Standards Agency (FSA), Environmental Agency (EA), Animal and Plant Health Agency (APHA), HMRC, MHRA, and Civil Aviation Authority (CAA).

Create a regulatory framework that is globally competitive and attractive. A joined-up approach to deep biotech regulation in the UK must not only lead to regulatory clarity and an improved regulatory process for deep biotech companies, but must ensure that the UK's regulatory framework for deep biotech is globally competitive with key markets (incl. the EU and US) and attractive to companies and investors. Close attention must also be paid to the benefits of regulatory convergence vs divergence with key markets. A strong, enabling, and supportive regulatory environment has a crowding-in effect, signalling to companies and investors alike to stay and grow there, and enabling companies to launch their products in the UK to the benefit of the UK's society, environment, and economy. Key areas where the UK can use regulation to create a competitive UK engineering biology ecosystem include, but are not limited to, a pro-innovation and product-based approach to the regulation of gene editing and genetic modification, microorganism-based products, novel foods, biological plant protection products, new bio-based plastics, and the NSI Act. The recent Genetic Technology (Precision Breeding) Act 2023 was a significant step in creating a UK competitive advantage, and must be enabled through secondary legislation.

Medicines regulation

The MHRA has long been recognised as a world-leading regulator, and during the pandemic it demonstrated its capacity to act in agile manner to enable rapid patient access to safe and effective treatments. The MHRA was also the first regulator in the world to approve Casgevy, a treatment for sickle-cell disease and transfusion-dependent β-thalassemia which uses the innovative gene-editing tool CRISPR.

However, following the agency's transformation resulting from the UK leaving the EU, capacity issues at the MHRA, which regulates medicines and medical devices in the UK, have caused delays across a range of services, including clinical trial and marketing authorisation applications and scientific advice meetings. Businesses are also hampered by duplication resulting from the UK's departure from the European regulatory system. Batch testing of medicines produced in the UK for export to Europe is one such example, which has not been addressed with the negotiation of a Mutual Recognition Agreement.

The BIA calls on Government to ensure that the MHRA is adequately resourced with expert assessors and financially sustainable in the long-term to deliver quality service. Greater predictability in review timelines is required to enable companies to plan their UK regulatory and clinical development strategy for the benefits of NHS patients.

We do not anticipate the need for major reforms to the regulation of medicines, given the MHRA's consultations on regulatory and legislative proposals with stakeholders and trade associations. We would recommend that Government does not introduce new rules which diverge considerably from EU medicines regulation to the detriment of the life sciences and biotech industry operating in the UK and EU.

It is important that medicines regulation is aligned with access and reimbursement processes to support faster access to treatments for patients in the NHS and improve the attractiveness of the UK as an early launch market for global biopharmaceutical companies. The Innovative Licensing and Access Pathway (ILAP), which is due to be relaunched in early 2025, has the potential to accelerate the time to patient care for transformative medicines. To deliver this ambition, all ILAP partners – the MHRA, UK Health Technology Assessment (HTA) bodies and the NHS – must have sufficient resources to dedicate to ILAP, while are also being able to deliver a quality service for medicines outside of ILAP. Innovative treatments for rare diseases could particularly benefit from the unique offering of ILAP in facilitating collaborative working between industry and health system partners.

Business Environment – Crowding in Investment

21. What are the main factors that influence businesses' investment decisions? Do these differ for the growth-driving sectors and based on the nature of the investment (e.g. buildings, machinery & equipment, vehicles, software, RDI, workforce skills) and types of firms (large, small, domestic, international, across different regions)?

Key points:

- A stable and predictable policy environment helps encourage business investment, as do fiscal incentives and support from government
- Account managers overseas play a key role in facilitating investment, whereas in the UK the journey is often made alone, increasing risk perception.

Our response to this question does not address equity investment into companies, as this is covered in response to the next question. However, it is worth noting that for pre-revenue start-ups and scale-ups, equity investment is almost the only way for them to get working capital, which then enables them to invest, primarily in R&D.

For life science and biotech companies, the question is generally not whether to invest, but where? Life sciences is an international industry funded with international capital. Moreover, it's highly in demand, with advanced economies across the globe competing for investment that brings both economic benefits and national security and resilience benefits. A stable and predictable policy environment helps give confidence to businesses to invest, as does government support via

initiatives such as R&D tax relief, high public R&D investment, a clear and stable regulatory framework, and strong intellectual property rights.

Despite the UK's strong R&D tax relief scheme, and a commitment from government that this support will continue, a recent report by RCK[49] demonstrated that the scheme is less generous compared to countries like Portugal, France, and Poland, making it comparably less effective and less accessible for companies. The UK also lags behind nations like the US, Germany, and Sweden in terms of Gross Domestic Expenditure on R&D (GERD) and Business Expenditure on R&D (BERD), with the lower levels of R&D investment potentially worsened by the less generous tax incentives.

What's more, whereas countries like Japan, Korea, and Germany have significantly increased their R&D budgets over the past decade, the UK's R&D budget has remained largely stagnant. In lieu of a more generous scheme, now is the time to target R&D tax relief for priority growth sectors like life science to ensure taxpayers' money is used properly to deliver economic growth and new innovations that benefit society and the world.

In addition, despite the new opportunity of manufacturing investment for high value sectors, opportunities within the UK for manufacturing are often lost to countries like Ireland, Singapore and the US. These countries operate a "single front door" approach to investment. The potential investors meet with key stakeholders from the area and have an account manager to help with land availability, planning permissions and energy grid connections. Account managers ensure the investor will have access to skills required to manufacture and market the product, and arrangements are often made for quality and manufacturing experts to meet with the clients. Competitive fiscal offers, such as grants or special tax rates are also often offered.

The Office for Investment, Department for Business and Trade and the Office for Life Sciences have built a strong "concierge" offer, which should continue to be expanded. It's important this is offered to domestic and foreign companies to secure investments in the UK. It is still very hard for companies who often do not know who to speak with in government and navigate these issues alone, making the investment feel like more of a risk. A continued focus on this is needed.

[49] Veselinov, M., and Willey, K. Comparative review of the UK's R&D Tax Relief scheme relative to other OECD countries. RCK & LBS. (2024).

Business Environment – Mobilising Capital

22. What are the main barriers faced by companies who are seeking finance to scale up in the UK or by investors who are seeking to deploy capital, and do those barriers vary for the growth-driving sectors? How can addressing these barriers enable more global players in the UK?

Key points:

- The UK life sciences sector lags behind the US in terms of investment, with the most significant gap seen in late-stage VC funding, although funding is a challenge in some subsectors
- Foreign investment dominates these funding rounds, which leads to high-value R&D, manufacturing and jobs moving abroad.
- Deep biotech companies also struggle at the seed stage, and a robust financing pipeline is needed to attract investment into the sector.
- This could be achieved via Innovate UK funds that are deep biotech-specific, and BPC should increase its focus on engineering biology and align with the National Vision for Engineering Biology and the new Regulatory Innovation Office (RIO).

Although the UK life sciences and biotech sector is a strong performer compared to European competitors (consistently accounting for approximately 30-40% of the continent's annual total venture investment[50]), compared to the US, the sector receives much lower levels of investment, even when accounting for GDP. The British Business Bank's latest Equity Tracker showed the US life sciences sector raises 59% more investment relative to GDP than the UK sector, and that this is the biggest sectoral funding gap seen in British venture capital.[51] The BBB's data also showed that UK life sciences is the only R&D-intensive UK sector that has not increased its market share of global venture investment over the last ten years.

Both BIA and BBB data shows seed funding for UK life sciences is relatively healthy, with levels comparable to the US.[52,53] However, early and late-stage VC (Series B+/£20m+) deals are where the gap opens up. Data from both the BIA and the British Venture Capital Association (BVCA) shows that investment at these stages – critical for scaling a business – is predominantly coming from foreign investors, particularly American ones.[54,55] This is also true for public markets, where there has been a significant trend since 2015 for UK life science companies to list on Nasdaq rather than the London Stock Exchange.[56] This is critical, as scaling businesses are drawn geographically to

[50] BIA: UK biotech financing 2023. (2023)
[51] British Business Bank: Small Business Equity Tracker 2024. (2024).
[52] BIA: UK biotech financing 2024. (2024).
[53] British Business Bank: Small Business Equity Tracker 2024. (2024).
[54] BIA: Finance report Q2 2024. (2024)
[55] BVCA and Beauhurst: UK scale-ups increasingly relying on overseas investors to grow. (2024).
[56] Unpublished BIA analysis available on request.

where they can access capital and be close to their investors. The UK therefore risks losing high value R&D, manufacturing, and management jobs as companies move overseas. Moreover, foreign equity investors participating in these later and larger financing rounds will collect the financial returns and pay capital gains taxes in their own jurisdictions, meaning wealth creation is not accumulated in the UK economy and reinvested in the next generation of scaling companies.

A focus is therefore needed on increasing the number of domestic investors, particularly large institutions like pension funds. The Mansion House Compact was an enormous step forward for the UK's financial services industry and has given hope to start-ups and scale-ups that the pensions industry is ready to engage with them and invest in their growth, in a way that foreign investors and pension funds already do.

Strong political leadership is required to drive this through, and we welcome the Chancellor's efforts so far. Carrot and stick policies may also be necessary. Given the strategic value of the sector to the UK's health and wealth, a "Life sciences charter" could be developed for pension funds to sign up to, committing them to invest into the sector to help create jobs and the medicines and other biotechnologies of the future that will improve all of our lives. BIA would be happy to help develop materials that could be used by the pensions industry to speak to their audiences about the good that they are doing for the UK's health and wealth.

Mandating pension funds to allocate a set percentage of assets under management to UK life sciences equities in return for state-subsidised pensions tax relief should also not be taken off the table as a last resort if the pensions industry behaviour does not change.

In conclusion, to ensure that pensions investment into UK assets reaches life sciences businesses to enable growth of this priority sector, the Pensions Review should:

- Deliver strong government leadership on the Mansion House Compact and championing of the life sciences sector within it, and use its convening power to drive forward commitments in the same way that the French Tibi scheme did
- Explore a life science-specific vehicle to provide an easy route through which pension funds can gain exposure to UK life science growth businesses
- Enhance the British Business Bank with additional funding, including enabling it to reinvest its profits, with a clear mandate to address market failures to support R&D intensive sectors
- Encourage the British Business Bank to publish data on the financial returns of the UK life sciences sector
- Explore a Life sciences charter for the pensions industry
- Not take off the table a mandatory requirement for pension funds to allocate a set percentage to the UK life science sector

Engineering biology & deep biotech

Looking at the sector more granularly, deep biotech companies can struggle to get investment at the early stages of their lifecycle, as well as scale-up finance. This may be due to the more nascent state of this subsector and applications of engineering biology. We need a pipeline of public funding interventions across different stages of companies' development, with a clear path to funding available from proof of concept to scale-up, which may vary across different sector applications of deep biotech. Importantly, we need deep biotech-specific Innovate UK funds that are non-competitive with other technologies and sectors. In addition, private investors need to be brought in early through investor partnerships linked to public funding programmes. This will lead to a strong funding and financing path for deep biotech companies, and will crowd in corporate venture capital.

British Patient Capital (BPC) should focus on R&D intensive businesses, and in collaboration with the National Wealth Fund, invest in relevant manufacturing and infrastructure needed to scale-up production of engineering biology products. BPC needs a greater focus on engineering biology as a priority area for the UK and to match the focus given to deep biotech by the National Vision for Engineering Biology and the new Regulatory Innovation Office (RIO), by establishing a dedicated engineering biology stream and team.

Financial policy levers need to be deployed that will increase investment into deep biotech, drive demand for its products and create market pull. The government must continue to implement the Mansion House Reforms to unlock capital that is key to delivering long-term strength in the UK venture financing ecosystem that most life science companies – and in turn, engineering biology companies – rely on.

23. The UK government currently seeks to support growth through a range of financial instruments including grants, loans, guarantees and equity. Are there additional instruments of which you have experience in other jurisdictions, which could encourage strategic investment?

Key points:

- Unlocking capital from pension funds for investment into innovative companies and VC funds can drive growth in the UK's life science sector, as modelled by Canda and Australia.
- A similar approach to France's Tibi Scheme could be taken in the UK to increase the interaction of institutional investors and VC funds, and channel any unlocked capital into the UK VC ecosystem.

As already noted, it is crucial to the long-term growth and sustainability of the UK biotech and life sciences sector, as well as other innovative sectors reliant on VC, to increase the number and scale of UK-based VC investors. To do this, new pools of institutional capital must be unlocked to invest in new UK VC funds. Unfortunately, UK institutional investors, including but not limited to pension

funds, in general are not attracted to riskier, high-growth industries. This is despite the returns it can deliver.

Australian and Canadian pension funds have structured themselves to be able to invest knowledgably and successfully in innovative life science opportunities in the UK and Europe in the last decade. They have learnt how to invest in innovation and scaled to employ in-house experts to understand emerging areas of science and technology. It is the outdated UK pensions industry that is holding back the allocation from Britain's investors and savers into British growth companies to support the science superpower ambition and drive economic growth.

The BIA has studied the French Tibi Scheme and believe a similar approach could be taken in the UK to increase the interaction of institutional investors and VC funds, and channel any unlocked capital into the UK VC ecosystem. The scheme was launched by the French government in 2020 to address the lack of willingness among its own institutional investment community to invest in the French tech industry. The scheme, championed by President Macron, secured the commitment of institutional investors to invest €6bn into French tech companies by December 2022. It was delivered through strong political involvement and the appetite of French institutional investors to support the country's strategic interests. Crucially, government spending was not required.

Institutional investors agreed to allocate a small proportion of their funds to VC firms accredited through the scheme. The institutions were then brought together with accredited VC firms and allowed to make their own decisions on which VC fund to invest in. We believe that by creating this opportunity for conversation between the UK's institutional investors and VC funds, both can adapt their investment strategies to suit each other's requirements and overcome the non-regulatory barriers to enable greater investment in VC. Such a scheme will need to be championed at the highest levels of government.

Business Environment – Trade and International Partnerships

24. How can international partnerships (government-to-government or government-to-business) support the Industrial Strategy?

The UK's life sciences sector is a truly global sector. R&D, business and investment partnerships between trusted international partners are a regular occurrence and critical to the functioning of the sector. International diplomacy and regulatory cooperation enable UK companies to access global markets for partnerships and export. As described in response to question 20, the UK's departure from the EU has hampered this where alignment or mutual recognition is no longer in place. Moreover, rising geopolitical tensions, national security and foreign policy changes in major global economies bring real risk of trade disruption in the years to come. Trade tariffs will also hold back the growth of UK life sciences, particularly our burgeoning manufacturing businesses.

In the UK's pursuit of entering trade agreements, including FTAs, with key markets and states including in the US and Asia, it is vital to uphold the UK's strong intellectual property regime to ensure UK life sciences businesses can predictably protect and enforce their IP rights on which they depend. Partnerships and mutual recognition agreements and memorandums of understanding between UK regulators, such as the MHRA, and regulatory counterparts of trusted international partners and key markets can speed up the approvals process for novel medicines and biotherapeutics.

The UK needs to strengthen its ties with the EU, by continuing to participate in Horizon Europe to ensure the UK's strengths in R&D and world-leading science, and work to ease the regulatory burden on UK companies seeking access to the European market. Regulatory divergence and convergence between the UK and the EU and other key markets such as the US needs to be carefully assessed in order to ensure a competitive UK market that attracts foreign investment and business, and allows companies with novel products and technologies to launch here.

The BIA works closely with the Department for Business and Trade to advise on international diplomacy and appreciates the support received. This partnership with UK industry is critical to ensuring the UK Government is able to fully and rightly advocate for British businesses.

25. Which international markets do you see as the greatest opportunity for the growth-driving sectors and how does it differ by sector?

The US and the EU are key markets for the UK's life sciences sector, in terms of attracting the right talent into biotech businesses, accessing investment, and for launching medicines and therapeutics.

The UK's deep biotech subsector will particularly benefit from access to the US, Japanese, and European markets, all of which have a renewed focus on creating incentives for pulling through biosolutions for a sustainable bioeconomy.

Place

28. How should the Industrial Strategy accelerate growth in city regions and clusters of growth sectors across the UK through Local Growth Plans and other policy mechanisms?

The life sciences and biotech sector has strong clusters of activity around London, Oxford and Cambridge, and the South East of England, as well as strengths in industrial biotechnology and manufacturing capacities in the north of England and Scotland. The industrial strategy should harness these existing regional and local strengths, through continued funding and political support.

UK BioIndustry Association

Partnerships and Institutions

31. How should the Industrial Strategy Council interact with key non-government institutions and organisations?

The Industrial Strategy Council should have business and SME representatives from each growth-driving sector and subsector, including deep biotech, as well as representations from those with expertise in foundational technologies, including engineering biology and other emerging biotechnologies.

The Council needs to work with the Life Sciences Council, which is an established and well-functioning official body, to ensure alignment across existing sector plans, and link up with and seek the expertise of other existing Councils and government-business groups such as trade advisory groups and sector-specific leadership councils.

The Life Sciences Council must continue but the Industrial Strategy Council should also work closely with industry bodies including the BIA to continuously seek views from the growth-driving life sciences businesses to inform the implementation of the industrial strategy. The Council should meet regularly and publish minutes from its meetings to ensure continued stakeholder engagement from businesses and organisations outside the Council.

Annex - Theory of Change

35. How would you monitor and evaluate the Industrial Strategy, including metrics?

Key points:

- Company creation, equity investment, R&D expenditure (in-house and outsourced), patenting and scientific publishing, and job creation are all valuable metrics and signs of high-growth businesses/subsectors at the cutting edge of their sector
- Government must be sure not to create perverse incentives when deciding metrics to measure in the Theory of Change

As described in our answer on the methodology, many traditional economic metrics are not well suited to the life sciences sector, especially R&D-intensive, pre-revenue biotech companies. However, such companies will be key to achieving the government's industrial strategy's desired impact, due to their disproportionate contribution to innovation and growth.

Company creation, equity investment, R&D expenditure (in-house and outsourced), patenting and scientific publishing, and job creation are all valuable metrics and signs of high-growth businesses/subsectors at the cutting edge of their sector, which will underpin economic growth.

The government also already collects and publishes many other metrics relevant to the life science sector's performance and productivity, as well as the health of the operating environment,

much of which is the result of government policy. These metrics include foreign direct investment, equity fundraising, clinical trial recruitment and export figures. They are collectively published in the Life sciences competitiveness indicators.[57]

When deciding metrics for the Theory of Change, the government must be sure not to create perverse incentives. This can happen when a metric is easier to achieve by supporting subsectors or businesses with certain characteristics, such as shorter timeframes to profit, even though they may not be the most sustainable and growth-enhancing subsectors or businesses in the long-term. This is particularly relevant when designing policy for start-ups and scale-ups (or SMEs) and biotech more broadly.

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[57] DHSC, OLS, DSIT: Life sciences competitiveness indicators 2024: summary. (2024).